EnCor Enspire™ Breast Biopsy System

JUN 16 2011

510(k) Summary of Safety and Effectiveness

21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

**Submitter Information:**

Applicant: SenoRx, Inc.
A Business Unit of Bard Peripheral Vascular, Inc.
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Contact: Justin Lovelace, Regulatory Affairs Specialist

Date: April 18, 2011

**Subject Device Name:**

| | |
|---|---|
| Device Trade Name: | EnCor Enspire™ Breast Biopsy System |
| Common or Usual Name: | Biopsy Instrument |
| Classification: | Class II (21 CFR 876.1075) |
| Classification Panel: | Gastroenterology & Urology |
| Product Code: | KNW |
| Predicate Device: | EnCor® Breast Biopsy System (K093512; Clearance November 20, 2009) |

**Device Description:**

The subject device is the EnCor Enspire™ Breast Biopsy System, an automated directional vacuum-assisted biopsy device consisting of an integrated control module and vacuum system with a detachable touch screen display. The key functional components of the EnCor Enspire™ Breast Biopsy System are integrated into a single console.

**Control Module** – The control module is designed to provide control operations and serve as an interface for drivers, probes and foot pedals.

- Inputs are delivered to the control module via either a driver or foot pedal.
- Based on the input received, the control module adjusts the motor speed of drivers and probes.
- System status is provided to the physician via an integrated LCD screen.

**Vacuum System** – During a breast biopsy procedure, the vacuum system draws the target tissue into the biopsy probe tissue acquisition chamber by creating a negative pressure differential at the tip of the probe being used. A disposable vacuum canister and disposable vacuum tubing cassette (with or without optional rinse tubing) is installed in the vacuum system at the time of each breast biopsy procedure.

**Touch Screen Display** – The touch Screen Display provides an intuitive user interface for the EnCor Enspire™ Breast Biopsy System. The display provides the system status and initiates operation of the installed driver and probe based on information and options entered or selected by the user.

**Indications for Use of Device:**

The EnCor Enspire™ Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities.

It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

It is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy.

When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g. fibroadenoma, fibrocystic lesion), the EnCor Enspire™ Breast Biopsy Systems may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

**Technological Comparison to Predicate Devices:**

The predicate device is the EnCor® Breast Biopsy System (K093512, cleared on November 20, 2009). It is referenced as the predicate device for the EnCor Enspire™ Breast Biopsy System because the two are substantially equivalent in terms of:

Intended Use

Indications for Use

Contraindications

Patient Population

Mechanics of Action

Mode of Action

Electrical Compatibility

Patient Contacting Materials

Available Accessories and Disposable Components

The subject device and the predicate device are different in the following manner:

The subject device integrates the major components of the predicate device (control module, vacuum system and cart) into a single assembly.

The subject device adds a large touch screen display with integrated graphical user interface software which replaces the small LCD screen display with integrated into the control module of the predicate device.

The subject device adds an adjustable tray to the body of the console.

The design of the single-use vacuum and rinse tubing sets has been changes to contain them in an ABS plastic housing.

**Performance Testing Summary:**

To demonstrate substantial equivalence of the subject device, the EnCor Enspire™ Breast Biopsy System to the predicate device, the technological characteristics and performance criterion were evaluated. Using the FDA draft guidance document, "Design Control Guidance for Medical Device Manufacturers" dated March 11, 1997, FDA guidance document "General Principles of Software Validation: Final Guidance for Industry and FDA Staff," issued January 11, 2002 and internal Risk Assessment procedures, the following non-clinical tests were performed:

- Vacuum Level
- Joint Tensile Strength
- Cassette Functionality
- Rinse Volume
- Cassette and Vacuum Reliability
- Packaging Validation
- User Validation
- Software Verification and Validation

The results from these tests demonstrate that the technological characteristics and performance criteria of the EnCor Enspire™ Breast Biopsy System are comparable to the predicate device and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

**Conclusions:**

The outcome of the risk management activities demonstrate the EnCor Enspire™ Breast Biopsy System presents an acceptable level of risk when used within its intended use. The RA, DFMEA, and design verification and validation activities demonstrate the design outputs of the subject device meet the device inputs and user need requirements.

In summary, the subject devise, the EnCor Enspire™ Breast Biopsy System, is substantially equivalent to the legally marketed predicate device, the EnCor® Breast

Biopsy System (K093512).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

C. R. Bard, Inc.
% Bard Peripheral Vascular, Inc.
Mr. Justin Lovelace
1415 West Third Street
Tempe, Arizona 85281-1740

JUN 16 2011

Re: K111100
Trade/Device Name: EnCor Enspire™ Breast Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: May 18, 2011
Received: May 19, 2011

Dear Mr. Lovelace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

**510(k) Number (if known):** K111100

**Device Name:** EnCor Enspire™ Breast Biopsy System

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111100

Prescription Use X AND/OR Over the Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)